WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| (51) International Patent Classification 6: | A1 | (11) International Publication Number: | WO 96/39948 |
|---|----|--|-----------------------------|
| A61B 17/04 | | (43) International Publication Date: | 19 December 1996 (19.12.96) |

(21) International Application Number: PCT/US96/08896

(22) International Filing Date: 5 June 1996 (05.06.96)

(30) Priority Data:
08/479,514
08/603,859
7 June 1995 (07.06.95)
US
22 February 1996 (22.02.96)
US

(71) Applicant: SMITH & NEPHEW ENDOSCOPY, INC. [US/US]; 160 Dascomb Road, Andover, MA 01810 (US).

(72) Inventors: EK, Steven, W.; 59 Bolton Woods Way, Bolton, MA 01740 (US). TORRIE, Paul, A.; 8 Bowden Street, Marblehead, MA 01945 (US). WALTON, Richard, E.; 161 Bridges Lane, North Andover, MA 01845 (US).

(74) Agents: DEVLIN, Peter, J. et al.; Fish & Richardson P.C., 225 Franklin Street, Boston, MA 02110 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

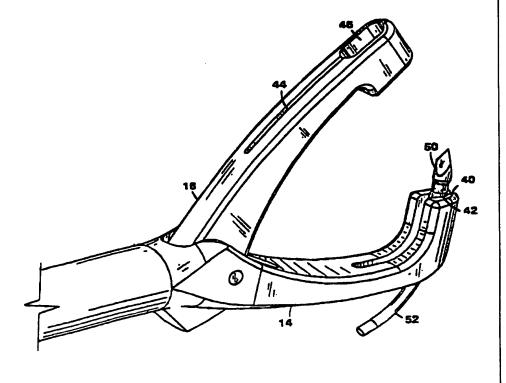
Published

With international search report.

(54) Title: SUTURE PASSING FORCEPS

(57) Abstract

A suture passing forceps includes an axially elongated support shaft (20), and a first suture holder (14) for removably holding a needled suture (30) and a second suture holder (16) for capturing the needled suture. The first suture holder includes a suture inlet (40) through which at least part of the suture can be passed. The first suture holder or the second suture holder is an actuatable member which pivots toward an operating position to capture the needled suture in the second suture holder and pivots away from the operating position to remove the suture from the first suture holder. The suture inlet in the suture holder enables complete removal of the suture from the suture holder when the actuatable member and the needled suture move away from the operating position. The second suture holder includes a holding region defined by a contoured surface permitting the needled suture to slide within the holding region.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | GB | United Kingdom | MW | Malawi |
|------|--------------------------|----|--|-----|--------------------------|
| AM | Armenia | GE | Georgia | MX | Mexico |
| TA | Austria | GN | Guinea | NE | Niger |
| ΑU | Australia | GR | Greece | NL | Netherlands |
| BB | Barbados | HU | Hungary | NO | Norway |
| BE | Belgium | IE | Ireland | NZ | New Zealand |
| BF | Burkina Faso | IT | Italy | PL | Poland |
| BG | Bulgaria | JP | Japan | PT | Portugal |
| ВJ | Benin | KE | Kenya | RO | Romania |
| BR | Brazil | | - | RU | Russian Federation |
| BY | Belarus | KG | Kyrgystan Democratic People's Republic | SD | Sudan |
| CA | Canada | KP | of Korea | SE | Sweden |
| CF | Central African Republic | | | SG | Singapore |
| CG | Congo | KR | Republic of Korea | S1 | Slovenia |
| СН | Switzerland | KZ | Kazakhstan | SK | Slovakia |
| CI | Côte d'Ivoire | LI | Liechtenstein | SN | Senegal |
| CM | Cameroon | LK | Sri Lanka | SZ | Swaziland |
| CN | China | LR | Liberia | TD | Chad |
| CS | Czechoslovakia | LT | Lithuania | TG | Togo |
| CZ | Czech Republic | LU | Luxembourg | LT. | Tajikistan |
| DE | Germany | LV | Larvia | ŤŤ | Trinidad and Tobago |
| DK | Denmark | MC | Monaco | UA | Ukraine |
| EE | Estonia | MD | Republic of Moldova | UG | Uganda |
| ES | Spain | MG | Madagascar | US | United States of America |
| FI | Finland | ML | Mali | | Uzbekistan |
| . FR | France | MN | Mongolia | L'Z | Viet Nam |
| GA | Gabon | MR | Mauritania | 12. | A 901 (A 971) |
| Un. | | | | | |

- 1 -

SUTURE PASSING FORCEPS Background of the Invention

The invention relates generally to suture forceps, 5 and more particularly, to a method and apparatus for passing needled sutures.

Current suturing instruments can include upper and lower jaws with a needle associated with the lower jaw. The jaws are used to punch the needle through the tissue 10 to be sutured and a suture thread is then fed through the needle, passing the suture thread from the lower jaw to the upper jaw. Other suturing instruments have been known in which a needle is pushed out of a lower jaw and through tissue, passed to an upper jaw, and held in place in the upper jaw with a spring.

Summary of the Invention

The invention relates to a suture passing forceps. The invention features an axially elongated support shaft, and a suturing assembly at a distal end of the 20 support shaft. The suturing assembly includes a first suture holder supported by the support shaft for removably holding a needled suture, and a second suture holder supported by the support shaft for passively capturing the needled suture. The suture holder includes 25 a suture inlet through which at least part of the suture can be passed. The first suture holder or the second suture holder is an actuatable member which pivots toward an operating position to passively capture the needled suture in the second suture holder and pivots away from 30 the operating position to remove the suture from the first suture holder. The suture inlet in the suture holder enables complete and free removal of the suture from the suture holder when the actuatable member and the needled suture move away from the operating position.

In particular embodiments of the invention, the second suture holder is the actuatable member. The first suture holder includes a holding region for removably holding a needle of the needled suture. The first suture 5 holder includes a jaw and the suture inlet is defined by a slot of a selected width in the jaw through which a suture thread of the needled suture can pass, the holding region being defined by an enlarged section of the slot into which the needle of the needled suture can be

10 placed. The holding region is oriented at an angle of about 90 degrees to an axis of the support shaft and the enlarged section of the slot is oriented to hold the needle at an outward angle of about 5 to 10 degrees to an axis normal to a longitudinal axis of the shaft to better engage the tissue to be sutured.

In the illustrated embodiment, the second suture holder includes a holding region having a spring force for removably holding a needle of the needled suture. Ir accordance with the invention, the second holding region defines a passive spring fit. The second suture holder includes a jaw having a slot of a selected width, the holding region being defined by an enlarged section of the slot and into which at least a portion of the needle can be spring fit, the relative sizes of the needle and the enlarged section of the second holding region defining, in part, the spring force.

The suture passing forceps include a handle at a proximal end of the support shaft, the handle being actuatable to move the actuatable member toward and away from its operating position.

In one illustrated embodiment, the second suture holder includes a window enabling a user to confirm that the suture has been passed from the first suture holder to the second suture holder.

- 3 -

In another illustrated embodiment, the first and second suture holders include inner surfaces that aid in preventing tissue hang-up thereon.

In accordance with the invention, a needled suture includes a suture thread and a sharp-tipped needle attached to a least one end of the suture thread. The needle includes a substantially straight body co-axially aligned with the suture thread. The body includes a holding portion having a different cross-sectional profile than portions of the body surrounding the holding portion. The body is substantially tubular-shaped. The needled has a length of less than about 0.5 inches.

According to another aspect of the invention, a suture anchor assembly includes an anchor for attachment to bone; at least one needled suture for use with the anchor, the needled suture including a suture thread and a substantially straight, sharp-tipped needle attached to a least one end of the suture thread. The needle includes a holding portion having a different cross-sectional profile than portions of the needle surrounding the holding portion. The suture thread may have a needle attached at each end.

A method of suturing, in accordance with the invention, includes the steps of punching a distal end of a needle of a needled suture through tissue to be sutured at a suture site thus creating a hole through the tissue through which a suture thread of the needled suture can pass; grabbing the distal end of the needle in a passive spring fit; moving the actuatable member away from the tissue being sutured to pull the suture thread through the suture hole without engaging a distal end of the suture thread; and removing only a needled end of the needled suture from the suture site by withdrawing the actuating member.

- 4 -

In accordance with the method of the invention, the punching is facilitated by actuation of the actuatable member pivoting toward its operating position. The needle is held in a suture holder during punching of the distal end of the needle through the tissue, the method including removing the needle from the suture holder by the action of grabbing the distal end of the needle with the actuatable member.

A method of minimally-invasively suturing deep

10 tissue through a portal includes anchoring a suture
thread having a needle attached thereto at each end to a
suture anchor, suturing a first tissue using a first of
the needled ends of the suture thread, and suturing a
second tissue using a second of the needled ends of the

15 suture thread, the suture thread, during both suturing
steps, always being anchored to the suture anchor.

According to another aspect of the invention, a suture passing forceps includes an axially elongated support shaft, and a suturing assembly at a distal end of 20 the support shaft. The suturing assembly includes a first suture holder supported by the support shaft for removably holding a needled suture, and a second suture holder supported by the support shaft for capturing the needled suture. The suture holder includes a suture 25 inlet through which at least part of the suture can be passed. The first suture holder or the second suture holder is an actuatable member which pivots toward an operating position to capture the needled suture in the second suture holder and pivots away from the operating 30 position to remove the suture from the first suture holder. The second suture holder includes a holding region partially defined by a contoured surface permitting the needled suture to slide within the holding region.

- 5 -

In particular embodiments of this aspect of the invention, the second suture holder is the actuatable member. The contoured surface is configured to facilitate removal of the needled suture from the holding region. The first suture holder includes a jaw and the suture inlet is defined by a slot of a selected width in the jaw through which a suture thread of the needled suture can pass. A needle holding region is defined by an enlarged section of the slot and a first portion of the enlarged section has a diameter greater than a diameter of the needle of the needled suture and a second portion of the enlarged section has a diameter less than the diameter of the needle. The slot is of limited depth extending from a surface of the jaw to the enlarged section.

According to another aspect of the invention, a method of suturing includes the steps of punching a distal end of a needle of a needled suture through tissue to be sutured at a suture site thus creating a hole 20 through the tissue through which a suture thread of the needled suture can pass; grabbing the distal end of the needle within a holding region in a first suture holder; pulling the suture through the suture hole without engaging a distal end of the suture thread; removing only a needled end of the needled suture from the suture site; and removing the needled suture from the first suture holder by sliding the needled suture along a contoured surface of the holding region.

In accordance with this aspect of the invention,

the punching is facilitated by actuation of the suture
holder pivoting toward its operating position. The
needle is held in a second suture holder during punching
of the distal end of the needle through the tissue and
the method includes removing the needle from the second

suture holder by the action of grabbing the distal end of

- 6 -

the needle with the first suture holder and moving the first suture holder away from the tissue. The distal end of the needle is grabbed in a passive spring fit within the holding region.

Brief Description of the Drawings

Other objects, features and advantages of the invention will be apparent from the following description taken together with the drawings in which:

Fig. 1 shows the suture passing forceps of the 10 invention with a needled suture;

5

Fig. 2 is a partially cut-away perspective view of the suturing assembly of the suture passing forceps of Fig. 1 shown in an open position;

Fig. 2A is a perspective view of the suturing 15 assembly of Fig. 1 shown in a closed position;

Fig. 3 shows a needled suture for use with the suture passing forceps of Fig. 1;

Fig. 4 shows the suturing assembly of Fig. 2 with the needled suture of Fig. 3;

20 Fig. 4A shows the suturing assembly of Fig. 4 in a first operating position;

Fig. 4B shows the suturing assembly of Fig. 4 in a second operating position;

Fig. 4C shows the suturing assembly of Fig. 4
25 after the needled suture has been passed through tissue;

Fig. 5 shows an alternative embodiment of the suturing assembly of the suture passing forceps of the invention;

Fig. 6 shows another alternative embodiment of the 30 suturing assembly of the suture passing forceps of the invention;

Fig. 7 shows an anchoring suture for use with the suture passing forceps of the invention;

- 7 -

Fig. 8 shows another alternative embodiment of the suturing assembly of the suture passing forceps of the invention;

Fig. 8A shows the suturing assembly of Fig. 8 in a 5 first operative position;

Fig. 8B shows the suturing assembly of Fig. 8 in a second operative position; and

Fig. 8C is an end view of a suture holder of Fig. 8B, taken along lines 8C-8C.

Description of the Preferred Embodiments

10

Referring to Fig. 1, according to the invention, a suture passing forceps 10 for use, e.g., in arthroscopic and endoscopic procedures, includes a suturing assembly 12 having a suture holder 14 for removably holding a

- 15 needled suture 30, and an actuatable member 16.

 Actuatable member 16 is pivotably supported by a support shaft 20. A handle 18 connected to support shaft 20 is used to actuate actuatable member 16. Handle 18 includes a stationary thumb section 22 and a movable finger
- 20 section 24. Movement of finger section 24 in the direction of an arrow 26 moves actuatable member 16 in the direction of an arrow 28 to an operating position adjacent the suture holder 14 (Fig. 2a). The reverse motion of finger section 24 returns actuatable member 16
- to its original position. An actuation mechanism such as used in the Smith & Nephew Dyonics 2.7 mm. Scoop, product #7204665, may be used. Suture passing forceps 10 include a suture tie off post 31, for example, a pin with an oring placed between a head of the pin and body 33 of
- 30 forceps 10. While the illustrated embodiment shows suture holder 14 as stationary and actuatable member 16 pivotably mounted, suture holder 14 can be pivotably mounted and actuatable member 16 stationary.

Referring to Figs. 2 and 2A, suture holder 14 35 includes a jaw 39 with a suture inlet slot 40 and a

- 8 -

needle holding region 42 for removably holding a needle of needled suture 30. Needle holding region 42 is defined by an enlarged area of slot 40 which extends from a distal end 42a of jaw 39 to a ledge 42b. Slot 40 cuts 5 through the entire region of jaw 39. Jaw 39 is oriented so that its axis 17 is about 90 degrees to a longitudinal axis 15 of support shaft 20. Holding region 42 is oriented to hold a needle of needled suture 30 at an angle α of about 5 to 10 degrees from axis 17 of jaw 39 10 to better enable a needle to engage the tissue to be sutured. As will be described in more detail below, slot 40 enables complete removal of needled suture 30 from suture holder 14 after passage of the needled suture through tissue. Actuatable member 16 includes a jaw 43 15 with a slot 44 having enlarged section 45 with a needle holding region 46 of smaller width than enlarged section 45. A ledge 46a in enlarged section 45 defines needle holding region 46.

A suture needle can be removably held within 20 suture holding region 42 of jaw 39. Slot 40 has a width of, e.g., about 0.021"; holding region 42 has a diameter of, e.g., about 0.034 - 0.035"; and needle 50 (see Fig. 3) has a diameter of, e.g., about 0.0315" - 0.0335". Needle 50 rests against ledge 42b of holding region 42 25 and suture thread 52 (see Fig. 4) passes through slot 40 and is tied off on post 31. Alternatively, holding region 42 can sized to produce a spring fit with needle Needle 50 can be held within holding region 46 of jaw 43 by the force of a passive spring fit. 30 relative sizes of the diameter or size of holding region 46 and the diameter of needle 50 in combination with the spring constant associated with the material of the jaw 43 define the spring force with which needle 50 is held within holding region 46. Slot 44 has a width of, e.g., 35 about 0.01"; holding region 46 has a width of, e.g.,

- 9 -

about 0.021" - 0.026" and a length of, e.g., about 0.06"; and a crimped area of the needle 50, described further below, has a width of, e.g., about 0.025" - 0.027". The holding force of actuatable member 16 on the needle is greater than the holding force of suture holder 14 on the needle. This difference in holding force enables the needle to be passed from suture holder 14 to actuatable member 16, as described below.

Referring to Fig. 3, needled suture 30 for use

10 with suture passing forceps 10 includes a needle 50 coaxially aligned with suture thread 52 and attached, e.g.,
by crimping or clamping, to suture thread 52 at an
attachment area 51. Needle 50 includes a substantially
straight, tubular shaped body 53 and a pointed distal tip

15 54 for ease of passage through tissue. The length of
needle 50 is less than about 0.5" and preferably about
0.3". It is the attachment area 51 that is held by
holding region 46 of actuatable member 16. Suture thread
52 may be, e.g., #1 or #2 size sutures, monofilament or
braided.

Referring to Figs. 4-4C, in use needle 50 of needled suture 30 is placed in suture holding region 42 by passing thread 52 through slot 40 and pulling on thread 52 to place needle 50 within holding region 42.

25 Handle 18 is actuated moving actuatable member 16 to the operating position shown in Fig. 4B, as needle 50 is pushed through the tissue 60 to be sutured. Closing of actuatable member 16 results in distal tip 54 of needle 50 being held within holding region 46 of actuatable

30 member 16 (Fig. 4B). Due to the greater holding force of holding region 46 of actuatable member 16 as compared to the holding force of holding region 42 of suture holder 14, when actuatable member 16 is moved to its open position, needle 50 is passed from suture holder 14 to actuatable member 16 (Fig. 4C). Suture thread 52 is then

free to pass through slot 40 to completely remove needled suture 30 from suture holder 14. Needle 50 can be pulled free from actuatable member 16 and suture thread 42 can then be cut and tied off.

Among the many advantages of the present suturing technique are passive capture of the needle within the holding regions, one-step suture passing, one-handed suturing action and complete removal of the needled suture from the suture holder after suture passing.

10 Referring to Fig. 5, in an alternative and preferred embodiment, suturing assembly 112 includes an actuatable member 116 having a window 148 through which needle 50 can be seen. Window 148 enables a user to confirm that the needle has been passed from suture 15 holder 114 to actuatable member 116.

Referring to Fig. 6, in an alternative embodiment, suture holder 214 and actuatable member 216 include inner surfaces 215, 217, respectively, that aid in preventing tissue hang-up during removal of the suture passing 20 forceps after needled suture 30 has been passed from suture holder 214 to actuatable member 216, as described above. Suture holder 214 includes a jaw 239 with a suture inlet slot 240 and a needle holding region 242 for removably holding a needle. Actuatable member 216 includes a jaw 243 with a slot 244 with an enlarged section 245 defining a needle holding region, as discussed above.

Referring to Fig. 7, the suture passing forceps of the invention can be used with a suture anchor 80 for 30 attachment to bone 84. A needled suture 82 passes through an opening of anchor 80. Needled suture 82 includes a suture thread 86 and a substantially straight, tubular-shaped, sharp-tipped needle 88, corresponding to needle 50 of Fig. 3, attached to one or both ends of suture thread 86.

PCT/US96/08896 WO 96/39948

- 11 -

In use during minimally-invasive suturing of deep tissue through a portal, suture thread 86 with needles 88 is passed through suture anchor 80, and, optionally, tied or crimped to suture anchor 80. A first tissue is 5 sutured using one of the needled ends of suture thread 86 and a second tissue is sutured using the other needled end of suture thread 86. During both suturing steps, suture thread 86 is always passing through suture anchor 80.

Referring to Figs. 8-8C, in an alternative and 10 preferred embodiment, a suturing assembly 312 includes an actuatable member 316 having a window 348 through which needle 50 can be seen. Window 348 enables a user to confirm that the needle has been passed from a suture 15 holder 314 to actuatable member 316. Actuatable member 316 includes first and second member halves 350, 352 having contoured inner surfaces 354 defining a needle holding region 346, and corresponding contoured outer surfaces 356 (only the contoured surfaces of member half 20 350 being shown). Needle holding region 346 may be created, for example, using electrical discharge machining using a ram shaped to create contoured inner surfaces 354. Halves 350, 352 define an open slot 344 between them into which needle 50 enters and is retained.

25

Referring particularly to Figs. 8A and 8B, needle 50 is passed through tissue 60 and initially is retained by actuatable member 316, as described previously. In this preferred embodiment of the invention, the needle is held, in a passive spring fit, between halves 350, 352 at 30 the edges 353a, 353b (Fig. 8) along a relatively flat region 370 of inner surfaces 354. It is the suture thread attachment area 51 of needle 50 which has a smaller diameter than a leading section 355 of the needle that is located between edges 353a, 353b. The actuatable 35 member 316 is opened (moved in the direction of arrow

PCT/US96/08896 WO 96/39948

358), and the entire suturing assembly 312 is pulled away from tissue 60 releasing suture thread 52 from suture holder 314 and pulling suture thread 52 through tissue 60.

During the opening motion of actuatable member 316, needle 50 advantageously slides within suture holding region 346 along slot 344 allowing needle 50 to align with the suture thread as the thread tugs on the needle. Contoured inner surfaces 354, and particularly 10 contoured region 372, allow the needle to slide within holding region 346 without creating any undesirable loads between needle 50 and member halves 350, 352 which may tend to pull needle 50 from the suture holding region. Additionally, contoured region 372 facilitates removal of 15 needle 50 from actuating member 316 by guiding attachment area 51 of needle 50 in the direction of arrow 360. Needle 50 is guided along inner surfaces 354 of actuating member 316 and exits from the top 345 (Fig. 8) of slot 344 by appropriate manipulation of actuatable member 316 20 and needled suture 30.

It is desirable that the radius of contoured region 372 be as large as possible while still preserving a length of flat region 370 that is long enough, for example about 0.04", to initially capture needle 50.

Referring to Figs. 8A and 8C, suture holder 314 includes an enlarged holding region 342 with a needle holding ledge 342b against which needle 50 rests when positioned in suture holder 314. A slot 340 extends from an external surface 314a of suture holder 314 to enlarged 30 region 342.

25

Additions, subtractions and other modifications of the illustrated embodiments of the invention will be apparent to those practiced in the art and are within the scope of the following claims.

- 13 -

What is claimed is:

10

A suture passing forceps, comprising:
 an axially elongated support shaft, and
 a suturing assembly at a distal end of said
 support shaft, including

a first suture holder supported by said support shaft for removably holding a needled suture, said first suture holder including a suture inlet through which at least part of the suture can be passed, and

a second suture holder supported by said support shaft for passively capturing said needled suture,

holder being an actuatable member pivotably supported for movement toward and away from an operating position to passively capture said needled suture in said second suture holder as the actuatable member moves toward the operating position, and to remove the needled suture from said first suture holder when said actuatable member 20 moves away from said operating position, said suture inlet in said first suture holder enabling complete removal of the suture from said first suture holder when said actuatable member and said needled suture move away from said operating position.

- 25 2. The suture passing forceps of claim 1 wherein said second suture holder comprises said actuatable member.
- The suture passing forceps of claim 1 wherein said first suture holder includes a holding region for
 removably holding a needle of the needled suture.
 - 4. The suture passing forceps of claim 3 wherein said first suture holder includes a jaw and said suture

- 14 -

inlet is defined by a slot of a selected width in said jaw through which a suture thread of the needled suture can pass, said holding region being defined by an enlarged section of said slot into which the needle of the needled suture can be placed.

- 5. The suture passing forceps of claim 4 wherein said holding region is oriented at an angle of about 90 degrees to an axis of said support shaft.
- 6. The suture passing forceps of claim 4 wherein said enlarged section of said slot is oriented to hold the needle at an outward angle of about 5 to 10 degrees to an axis normal to a longitudinal axis of the support shaft.
- 7. The suture passing forceps of claim 1 wherein 15 said second suture holder includes a holding region having a spring force for removably holding a needle of the needled suture.
 - 8. The suture passing forceps of claim 7 wherein said holding region defines a passive spring fit.
- 9. The suture passing forceps of claim 7 wherein said second suture holder includes a jaw defining a slot of a selected width, said holding region being defined by an enlarged section of said slot into which at least a portion of the needle can be spring fit, the relative sizes of said needle and said enlarged section of said holding region defining, in part, said spring force.
 - 10. The suture passing forceps of claim 1 further including a handle at a proximal end of said support shaft, said handle being actuatable to move said

- 15 -

actuatable member toward and away from its operating position.

- 11. The suture passing forceps of claim 1 wherein said second suture holder further comprises a window 5 enabling a user to confirm that the suture has been passed from said first suture holder to said second suture holder.
- 12. The suture passing forceps of claim 1 wherein said first and second suture holders include inner
 10 surfaces that aid in preventing tissue hang-up thereon.
 - 13. A suture passing forceps, comprising:
 an axially elongated support shaft, and
 a suturing assembly at a distal end of said
 support shaft, including
- a suture holder supported by said support
 shaft and including a jaw and a suture inlet defined by a
 slot of a selected width in said jaw through which a
 suture thread of the needled suture can pass, and a
 holding region defined by an enlarged section of said
 slot for removably holding a needle of a needled suture,
 and

an actuatable member pivotably supported for movement toward and away from an operating position to passively capture said needled suture as the actuatable member moves toward the operating position, and to remove the needled suture from said suture holder when said actuatable member moves away from said operating position, said suture inlet in said suture holder enabling complete removal of the suture from said suture holder when said actuatable member and said needled suture move away from said operating position, said actuatable member including a jaw defining a slot of a

- 16 -

selected width, a second holding region being defined by an enlarged section of said slot into which at least a portion of the needle can be spring fit, the relative sizes of said needle and said enlarged section of said bolding region defining, in part, a spring force.

- 14. A needled suture, comprising:
- a suture thread, and
- a sharp-tipped needle attached to a least one end of said suture thread, said needle having a substantially straight body co-axially aligned with said suture thread, said body including a holding portion having a different cross-sectional profile than portions of said body surrounding said holding portion.
- 15. The needled suture of claim 14 wherein said 15 body is substantially tubular-shaped.
 - 16. The needled suture of claim 14 wherein said needle has a length of less than about 0.5 inches.
 - 17. A suture passing forceps for passing a needled suture, comprising:
- an axially elongated support shaft, and
 a suturing assembly at a distal end of said
 support shaft, including
- a first suture holder supported by said support shaft for removably holding a needled suture, 25 said first suture holder including a suture inlet through which at least part of the suture can be passed, and
 - a second suture holder supported by said support shaft for passively capturing said needled suture,
- said first suture holder or said second suture holder being an actuatable member pivotably supported for

- 17 -

movement toward and away from an operating position to passively capture said needled suture in said second suture holder as the actuatable member moves toward the operating position, and to remove the needled suture from 5 said first suture holder when said actuatable member moves away from said operating position, said suture inlet in said first suture holder enabling complete removal of the suture from said first suture holder when said actuatable member and said needled suture move away from said operating position,

said needled suture comprising:

a suture thread, and

a sharp-tipped needle attached to a least one end of said suture thread, said needle having a

15 substantially straight body co-axially aligned with said suture thread, said body including a holding portion having a different cross-sectional profile than portions of said body surrounding said holding portion.

- 18. A suture anchor assembly, comprising: an anchor for attachment to bone,
- at least one needled suture for use with said anchor, said needled suture, comprising:
 - a suture thread, and

20

- a substantially straight, sharp tipped needle

 25 attached to a least one end of said suture thread, said
 needle including a holding portion having a different
 cross-sectional profile than portions of said needle
 surrounding said holding portion.
- 19. The suture anchor assembly of claim 18
 30 wherein said suture thread has said needle attached to each end of said suture thread.
 - 20. A method of suturing comprising the steps of:

- 18 -

punching a distal end of a needle of a needled suture through tissue to be sutured at a suture site thus creating a hole through the tissue through which a suture thread of said needled suture can pass,

actuating an actuatable member to grab said distal end of said needle in a passive spring fit,

moving said actuatable member away from the tissue being sutured to pull said suture thread through said suture hole without engaging a distal end of said suture thread, and

removing only a needled end of said needled suture from said suture site by withdrawing said actuating member.

- 21. The method of claim 20 wherein said punching 15 is facilitated by actuation of said actuatable member pivoting toward its operating position.
- 22. The method of claim 20 wherein said needle is held in a suture holder during punching of the distal end of said needle through the tissue, said method including removing said needle from said suture holder by the action of grabbing said distal end of said needle with said actuatable member and moving said member away from said tissue.

suturing a first tissue using a first of said needled ends of said suture thread, and

suturing a second tissue using a second of said needled ends of said suture thread,

- 19 -

said suture thread, during said both suturing steps, always being anchored to said suture anchor.

24. A suture passing forceps, comprising: an axially elongated support shaft, and a suturing assembly at a distal end of said support shaft, including

5

a first suture holder supported by said support shaft for removably holding a needled suture, said suture holder including a suture inlet through which 10 at least part of the suture can be passed, and

a second suture holder supported by said support shaft for capturing said needled suture,

said first suture holder or said second suture holder being an actuatable member pivotably supported for movement toward and away from an operating position to capture said needled suture in said second suture holder as the actuatable member moves toward the operating position, and to remove the needled suture from said first suture holder when said actuatable member moves away from said operating position, said second suture holder including a holding region partially defined by a contoured surface permitting the needled suture to slide within said holding region.

- 25. The suture passing forceps of claim 24 25 wherein said second suture holder comprises said actuatable member.
- 26. The suture passing forceps of claim 24 wherein said contoured surface is configured to facilitate removal of said needled suture from said 30 holding region.

- 20 -

- 27. The suture passing forceps of claim 24 wherein said second suture holder passively captures said needled suture.
- 28. The suture passing forceps of claim 27 by wherein said holding region has a spring force for removably holding a needle of the needled suture.
 - 29. The suture passing forceps of claim 28 wherein said holding region defines a passive spring fit.
- 30. The suture passing forceps of claim 29

 10 wherein said second suture holder includes a jaw defining a slot of a selected width, said holding region being defined by an enlarged section of said slot into which the needle can be spring fit, the relative sizes of said needle and said enlarged section of said holding region

 15 defining, in part, said spring force.
- wherein said suture inlet in said first suture holder enables complete removal of the suture from said first suture holder suture holder when said actuatable member and said needled suture move away from said operating position.
- wherein said first suture holder includes a jaw and said suture inlet is defined by a slot of a selected width in said jaw through which a suture thread of the needled suture can pass, a needle holding region being defined by an enlarged section of said slot, a first portion of said enlarged section having a diameter greater than a diameter of the needle of the needled suture and a second portion of said enlarged section having a diameter less than the diameter of the needle.

- 21 -

33. The suture passing forceps of claim 32 wherein said slot is of limited depth extending from a surface of said jaw to said enlarged section.

34. A suture passing forceps for passing a 5 needled suture, comprising:

an axially elongated support shaft, and a suturing assembly at a distal end of said support shaft, including

a first suture holder supported by said

10 support shaft for removably holding a needled suture,
said suture holder including a suture inlet through which
at least part of the suture can be passed, and

a second suture holder supported by said support shaft for capturing said needled suture,

said first suture holder or said second suture holder being an actuatable member pivotably supported for movement toward and away from an operating position to capture said needled suture in said second suture holder as the actuatable member moves toward the operating position, and to remove the needled suture from said first suture holder when said actuatable member moves away from said operating position, said second suture holder including a holding region defined by a contoured surface permitting the needled suture to slide within

25 said holding region,

said needled suture comprising:

a suture thread, and

a sharp-tipped needle attached to a least one end of said suture thread, said needle having a substantially straight body co-axially aligned with said suture thread, said body including a holding portion having a different cross-sectional profile than portions of said body surrounding said holding portion.

- 22 -

35. A method of suturing comprising the steps of:
punching a distal end of a needle of a needled
suture through tissue to be sutured at a suture site thus
creating a hole through the tissue through which a suture
thread of said needled suture can pass,

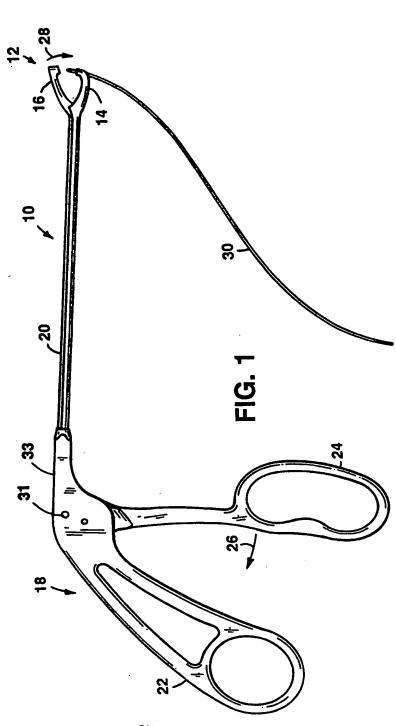
grabbing said distal end of said needle within a holding region in a first suture holder,

pulling said suture thread through said suture hole without engaging a distal end of said suture thread,

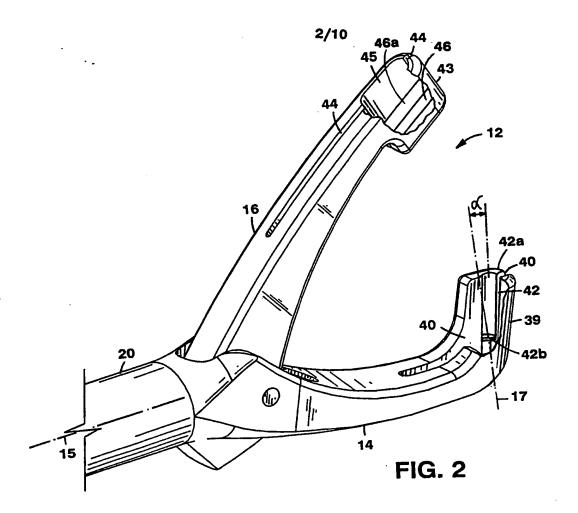
removing only a needled end of said needled suture from said suture site, and

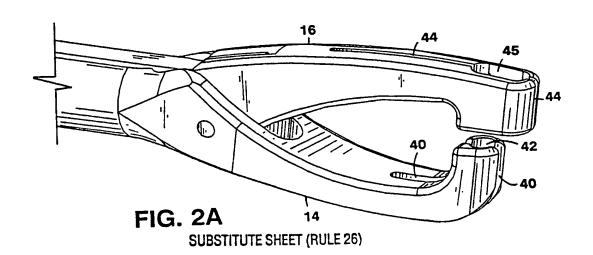
removing said needled suture from said first suture holder by sliding said needled suture along a contoured surface of said holding region.

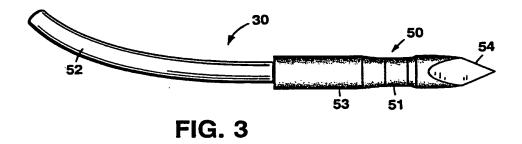
- 15 36. The method of claim 35 wherein said punching is facilitated by actuation of said suture holder pivoting toward an operating position.
- 37. The method of claim 35 wherein said needle is held in a second suture holder during punching of the distal end of said needle through the tissue, said method including removing said needle from said second suture holder by the action of grabbing said distal end of said needle with said first suture holder and moving said first suture holder away from said tissue.
- 25 38. The method of claim 35 wherein said distal end of said needle is grabbed in a passive spring fit within said holding region.

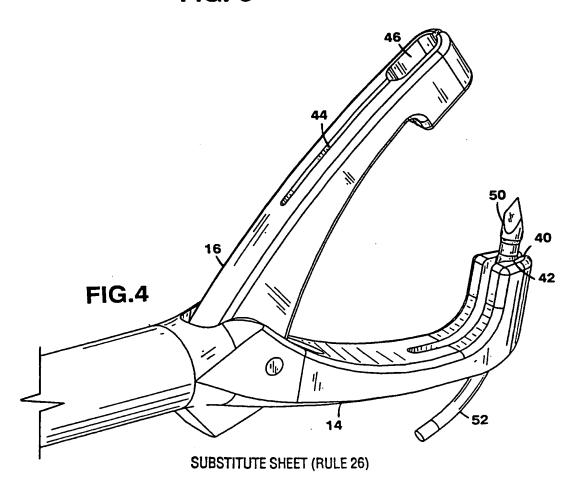


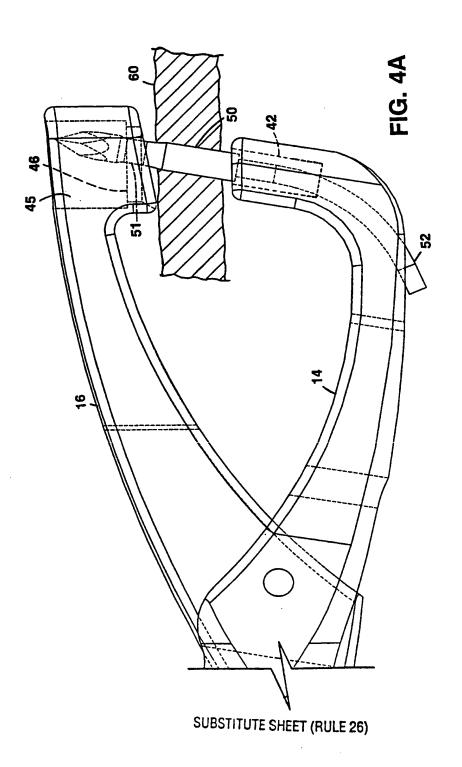
SUBSTITUTE SHEET (RULE 26)

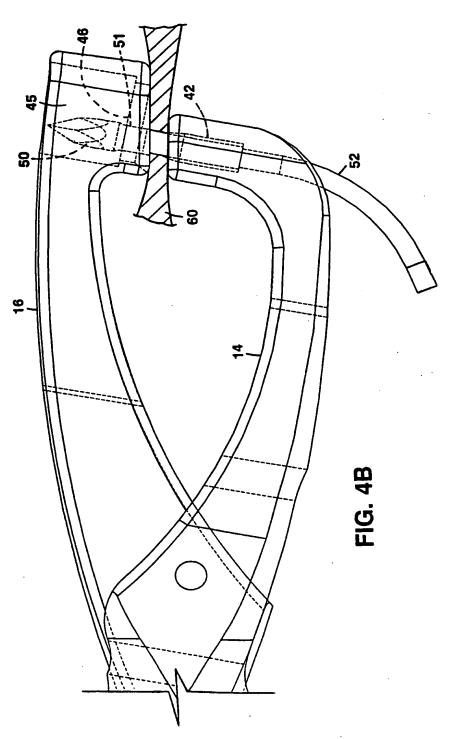












SUBSTITUTE SHEET (RULE 26)

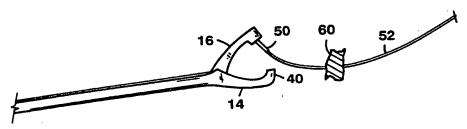
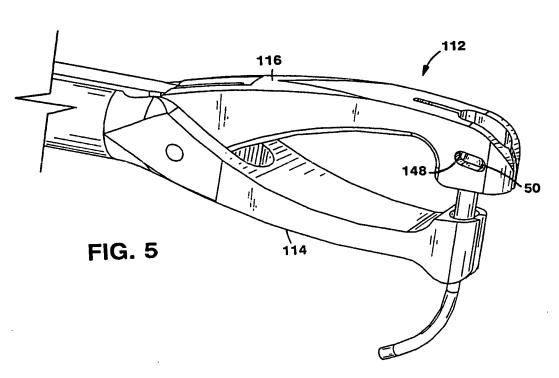
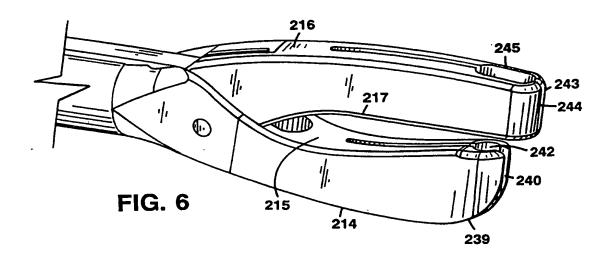
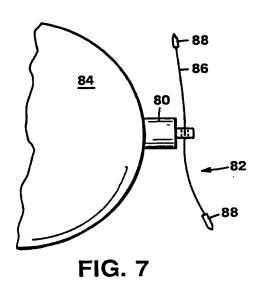


FIG. 4C

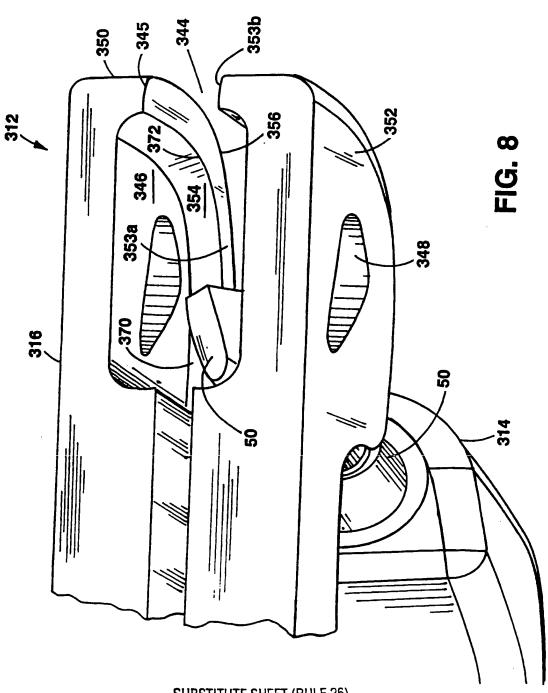


SUBSTITUTE SHEET (RULE 26)

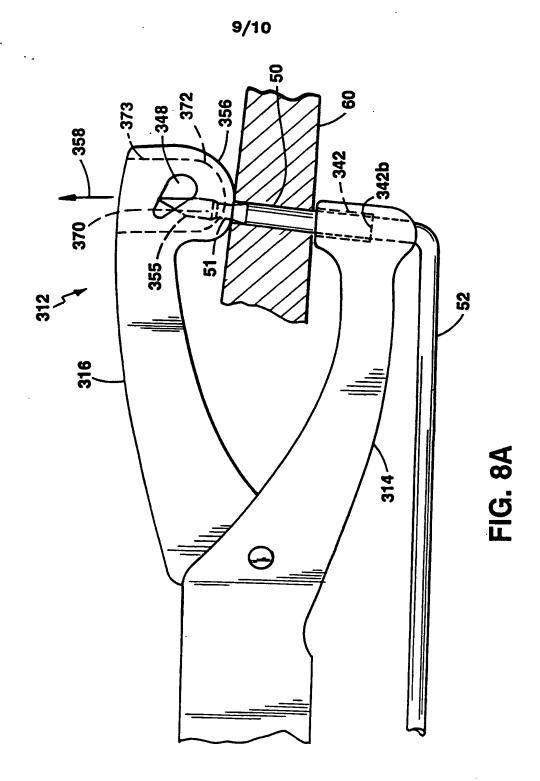




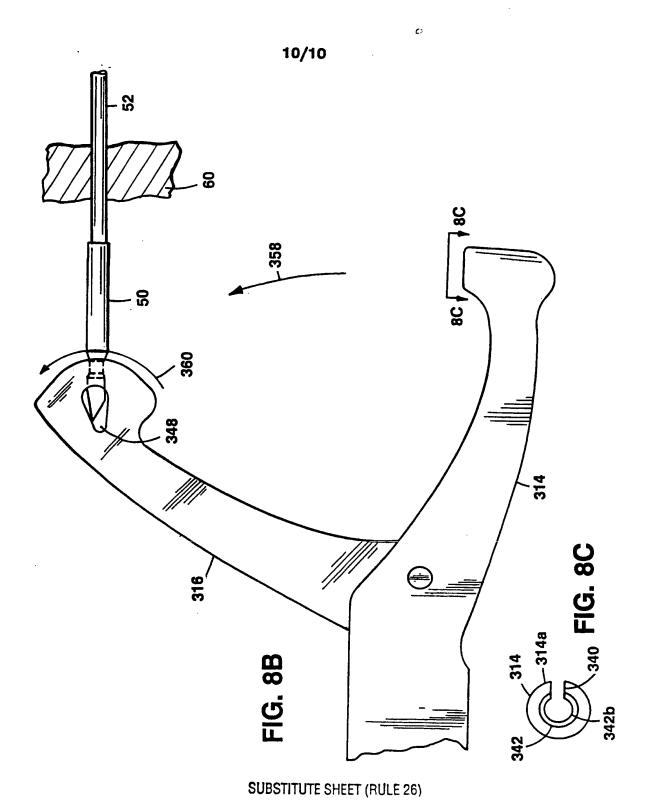
SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/08896

| A. CLASSIFICATION OF SUBJECT MATTER | | | | | | | |
|--|--|---------------------------------------|-----------------------------|--|--|--|--|
| IPC(6) :A61B 17/04 US CL :606/144, 145, 147, 148 | | | | | | | |
| According to International Patent Classification (IPC) or to both national classification and IPC | | | | | | | |
| B. FIELDS SEARCHED | | | | | | | |
| Minimum documentation searched (classification system followed by classification symbols) | | | | | | | |
| U.S. : 1 | 128/898; 606/139, 144-148, 222- 224, 232 | | | | | | |
| Documentati | ion searched other than minimum documentation to the extent that | such documents are included | in the fields searched | | | | |
| Electronic da | ata base consulted during the international search (name of data | base and, where practicable, | search terms used) | | | | |
| c. Doci | UMENTS CONSIDERED TO BE RELEVANT | | | | | | |
| Category* | Citation of document, with indication, where appropriate, o | f the relevant passages | Relevant to claim No. | | | | |
| x | US, A, 3,349,772 (I. H. RYGG) 31 O | ctober 1967, see | 1-13, 24-33 | | | | |
| Y | entire document. | | 14-23, 34-38 | | | | |
| Y | US, A, 5,224,955 (WEST) 06 July 1993 3. | 14-19, 34 | | | | | |
| | US, A, 5,259,846 (GRANGER ET AL.) 09 see Fig. 1. | 18, 19 | | | | | |
| A | US, A, 5,382,257 (LEWIS ET AL.) 17 Ja | 1-19, 24-34 | | | | | |
| Y | US, A, 4,890,615 (CASPARI ET AL.) 02 January 1990, see entire document, and Figs. 11-16. | | | | | | |
| | | | | | | | |
| X Furthe | er documents are listed in the continuation of Box C. | See patent family annex. | | | | | |
| | -A- | ter document published after the inte | | | | | |
| 'A' docu to be | present outsiming the general state of the art which is not considered pr | inciple or theory underlying the inve | ntion | | | | |
| e cartier document published on or after the international filing date "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone. | | | | | | | |
| cited | to establish the publication date of another citation or other inl reason (as specified) | cument of particular relevance; the | claimed invention cannot be | | | | |
| O" document referring to an oral disclosure, use, exhibition or other combined with one or more other such documents, such combination | | | | | | | |
| P docu | | | | | | | |
| Date of the actual completion of the international search Date of mailing of the international search | | | | | | | |
| 15 JULY 1996 29 AUG 1996 | | | | | | | |
| Name and mailing address of the ISA/US Apthorized offices | | | | | | | |
| Commissioner of Patents and Tredemarks Box PCT Washington, D.C. 20231 PATRICK RASCHE | | | | | | | |
| | . (703) 305-3590 Telephone I | No (703) 308-3523 | | | | | |

THIS PAGE BLANK (USPTO)